



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Draft Guidance for Industry on Bioequivalence Recommendations for Iron Sucrose; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Bioequivalence Recommendations for Iron Sucrose." The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for iron sucrose injection. The draft guidance is a revised version of a previously issued draft guidance on the same subject.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris Andre, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8866.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for iron sucrose injection (Draft Iron Sucrose Injection BE Recommendations of 2013).

Venofer (iron sucrose injection), new drug application 021135, was initially approved by FDA in November 2000. There are no approved ANDAs for this product.

In March 2012, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for iron sucrose injection (Draft Iron Sucrose Injection BE Recommendations of 2012). In that draft guidance, FDA recommended an

in vivo fasting BE study with pharmacokinetic endpoints and in vitro studies. FDA has reconsidered the recommendations in the Draft Iron Sucrose Injection BE Recommendations of 2012 and has decided to revise it. At this time, FDA is withdrawing the Draft Iron Sucrose Injection BE Recommendations of 2012 and is issuing a revised draft guidance for industry, the Draft Iron Sucrose Injection BE Recommendations of 2013. In this revised draft guidance, FDA recommends that for the in vivo pharmacokinetic study the difference between total iron and transferrin-bound iron be used to demonstrate BE of generic iron sucrose injection products. FDA is no longer recommending baseline-adjusted total iron and baseline-adjusted transferrin-bound iron be used to demonstrate BE of generic iron sucrose injection products. The revised draft guidance also provides updated information about the recommended studies for in vitro characterization and criteria for waiver of in vivo testing.

In March 2005, Luitpold Pharmaceuticals, Inc. (Luitpold), manufacturer of the reference listed drug, Venofer, submitted (through its attorneys) a citizen petition requesting that FDA withhold approval of any ANDA or 505(b)(2) application for a generic iron sucrose injection unless certain conditions were satisfied, including conditions related to demonstrating BE (Docket No. FDA-2005-P-0319, formerly 2005P-0095/CP1). FDA is reviewing the issues raised in the petition and is also reviewing the supplemental information and comments that have been submitted to the docket for that petition. FDA will consider any comments on the Draft Iron Sucrose Injection BE Recommendations of 2013 before responding to Luitpold's citizen petition.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for iron sucrose injection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.